



U.S. Immigration
and Customs
Enforcement

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News Release

The Skin and Vein Center pleads guilty to importing non-FDA-approved medical devices

DETROIT — The Skin and Vein Center pleaded guilty here Wednesday to unlawfully importing goods into the United States, announced U.S. Attorney Stephen J. Murphy, Eastern District of Michigan; Michael E. Cleary, special agent-in-charge of the Food and Drug Administration (FDA), Office of Criminal Investigations; and Brian M. Moskowitz, special agent-in-charge, U.S. Immigration and Customs Enforcement (ICE).

The Skin and Vein Center, aka “Dermatology Pathology, P.C.,” has offices located in Troy, Westland, Southfield and Fenton, Mich.

Dr. Eric Seiger previously entered a guilty plea on July 5 before U.S. District Judge Denise Page Hood. Seiger pleaded guilty to the misdemeanor offense of introducing a misbranded medical device into commerce. The plea was entered on behalf of the company by Dr. Eric Seiger, a 50-percent shareholder in the Skin and Vein Center (SVC).

“Members of the public must be able to trust that their doctor will not be administering drugs or treatments that are not approved by the FDA. Medical professionals, above all, will be held accountable if they intentionally misuse or administer unapproved drugs. I commend the FDA’s Office of Criminal Investigations, and ICE for their excellent investigation that led to this prosecution,” said U.S. Attorney Murphy.

According to Brian M. Moskowitz, special agent in charge of U.S. Immigration and Customs Enforcement (ICE), Office of Investigations in Detroit, “These guilty pleas result from an aggressive investigative partnership between the FDA and ICE. There is an obvious safety concern regarding illegally importing and subsequently using unlicensed medications and/or medical devices. ICE will continue to aggressively pursue individuals and organizations involved with illegally importing goods that may jeopardize the safety of our communities.”

Skin and Vein Center ("SVC") is engaged in the business of providing office-based dermatological surgery and care, hair transplantation and varicose vein treatment. SVC is owned and managed by Dr. Sandy Goldman and Dr. Eric Seiger.

On Sept. 2, 2004, federal agents executed search warrants at SVC's four business locations. "Perlane" was one of the items noted on the search warrant and specified to the office manager at the Fenton location. However, during execution of the search warrant, the office manager attempted to hide quantities of Perlane in a locked shredder box in order to prevent the agents from discovering and seizing the Perlane. Perlane is a substance that was not then approved by the FDA, and was being used as a dermatological filler to enlarge lips or reduce wrinkles.

Beginning in 2003, SVC unlawfully imported the medical devices Restylane and Perlane into the United States and administered them to its patients. Both Restylane and Perlane are temporary dermatological fillers administered via injection to enhance the recipient's appearance by, for example, enlarging the lips or minimizing facial lines and wrinkles. Restylane and Perlane are classified under federal law as Class III medical devices. Restylane was first approved by the U.S. Food and Drug Administration (FDA) on Dec. 12, 2003. Perlane was not approved by the FDA for any purpose before Sept. 4, 2004. Prior to those respective times, as unapproved Class III medical devices, it was illegal to import or introduce Restylane or Perlane into commerce.

Knowing that Perlane and Restylane were not approved by the FDA, and knowing that their distributor would not ship either device to the United States, Seiger initiated a scheme to obtain Perlane in Canada.

Initially, Seiger made arrangements for shipments of Restylane and Perlane to be delivered to a location in Windsor, Canada. On two occasions, Seiger sent an SVC employee to Windsor to pick up the packages of Restylane and Perlane and bring the packages back to SVC's Troy location. On each occasion, Seiger paid the employee \$100 in cash from his personal funds. Seiger gave the employee explicit instructions to deny knowledge of the contents of the packages in the event the employee was questioned by U.S. Customs and Border Protection (CBP) officials.

Seiger made arrangements for Restylane and Perlane to be shipped directly to SVC via a dentist's office in Pickering, Ontario. Whenever SVC needed more Restylane and Perlane, Seiger contacted the distributor directly and, while claiming to be a representative of the dentist's office, ordered more Restylane and Perlane on the dentist's account. After the Restylane and Perlane arrived at the dentist's office, an employee of the dentist shipped the Restylane and Perlane to SVC's Troy location. On some such occasions, the employee mislabeled the packages as containing dental bleach.

The count to which SVC pleaded guilty carries a maximum sentence of a \$500,000 fine. The count to which Seiger pleaded guilty carries a maximum sentence of one year in prison and/or a \$100,000 fine.

As part of the agreements reached with the government, SVC has agreed to forfeit \$412,048.61 to the U.S. Government.

The sentencing for Seiger and SVC is scheduled for Nov. 9.

Assistant U.S. Attorney Sarah Resnick-Cohen, Eastern District of Michigan, prosecuted this case.

ICE

U.S. Immigration and Customs Enforcement was established in March 2003 as the largest investigative arm of the Department of Homeland Security. ICE is comprised of four integrated divisions that form a 21st century law enforcement agency with broad responsibilities for a number of key homeland security priorities.